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PARCUS Medical, LLC

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## 510(k) Summary


**Submitter:** Parcus Medical, LLC
839 South Neenah Ave.
Sturgeon Bay, WI 54234


MAR 6 2009


**Company Contact:** Barton Bracy
Phone: (920) 746-2972
Fax: (920) 746-8665


**Date Prepared:** December 1, 2008

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**Trade Name:** Parcus Titanium Interference Screw

**Common Name:** Interference Screw

**Classification Name:** Fastener, Fixation, Non-Degradable, Soft Tissue
21 CFR 888.3040 – Product Code HWC and MBI

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**Predicate Devices:**

- Arthrex Interference Screw (K062466)
- Smith & Nephew BioRCI Screw (K032224)
- Smith & Nephew Titanium Interference Screws (K040331)

**Device Description:**

The Parcus Titanium Interference Screw is a cannulated, threaded, tapered fastener for use in interference fixation of ligaments and tendons in patients requiring ligament or tendon repair. The device is made from a Titanium alloy, Ti-6Al-4V ELI (ASTM F136) and is available in sizes ranging from 7-12mm in diameter and 20-35mm in length.

**Intended Use:**

The Parcus Titanium Interference Screw is indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

**Substantial Equivalence Summary:**

The Parcus Titanium Interference Screw is substantially equivalent to the predicate devices listed above in which the basic features and intended uses are the same. Any differences between the Titanium Interference Screw and the predicate devices are considered minor and do not raise questions concerning safety and effectiveness.

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**Summary Performance Data:**

The pull out strength and insertion torque was measured for the smallest (7mm) and largest (12mm) Parcus Titanium Interference Screws as well as an intermediate size. Side by side comparisons were done with the predicate devices and results of the insertion torque testing and pullout force demonstrated that there were no significant differences between the Parcus Titanium Interference Screw and the predicate devices.



839 S NEENAH AVE., STURGEON BAY, WI 54235 >> 1-877-746-2972 >> www.parcusmedical.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Parcus Medical, LLC
% Mr. Barton Bracy
839 South Neenah Avenue
Sturgeon Bay, Wisconsin 54234

MAR 6 2009

Re: K083619
Trade/Device Name: Parcus Titanium Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, MBI
Dated: December 1, 2008
Received: December 8, 2008

Dear Mr. Bracy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

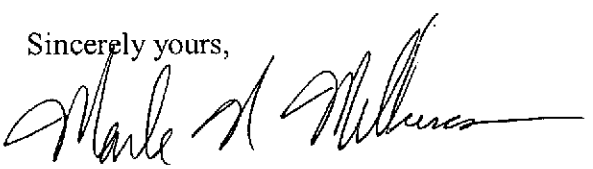
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

**510(k) Number (if known):** K083619

**Device Name:** Parcus Titanium Interference Screw

**Indications for Use:**

The Parcus Titanium Interference Screw is indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

Prescription Use __X__ AND/OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083619